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Patent
Attorney Docket No. 032,290-007
(formerly ARTM 1000-6US)

#19
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Fulton, et al.

Patent No: 6,730,042 B2
Issued: May 4, 2004

Serial No.: 10/027,157
Filed: December 20, 2001

Title: BIOPSY LOCALIZATION METHOD AND DEVICE

TRANSMITTAL OF REQUEST FOR CERTIFICATE OF CORRECTION

Mail Stop: Certificate of Correction Branch
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed for filing, please find the following:

1. Request for Certificate of Correction of Patent for Office Mistake (37 CFR 1.322(a)) and Applicant's Mistake (37 CFR 1.323);

2. Certificate of Correction (Form PTO/SB/44); and

3. COPY of Amendment and Response dated December 1, 2003 and Response dated February 9, 2004.

CERTIFICATE OF MAILING (37 C.F.R. §1.8a)

I hereby certify that I have reasonable basis to expect and believe that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

June 3, 2004
Date of Deposit

Cynthia B Pacheco
Cynthia B. Pacheco

IR1:1055442.1

4. The Commissioner is hereby authorized to charge Deposit Account No. 50-2862 in the amount of $100.00. The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayments to Deposit Account 50-2862.

Please send the Certificate to:

John Kappos, Esq.
O'Melveny & Myers LLP
114 Pacifica, Suite 100
Irvine, CA 92618

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: June 3, 2004

By: Diane K. Wong
Diane K. Wong
Reg. No. 54,550

DKW/kmg
Enclosures

114 Pacifica, Suite 100
Irvine, CA 92618
(949) 737-2900

Patent
Attorney Docket No. 032,290-007
(formerly ARTM 1000-6US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Fulton, et al.

Patent No: 6,730,042 B2
Issued: May 4, 2004

Serial No.: 10/027,157
Filed: December 20, 2001

Title: BIOPSY LOCALIZATION METHOD AND DEVICE

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR OFFICE MISTAKE (37CFR 1.322(a)) AND APPLICANT'S MISTAKE (37 CFR 1.323)

Mail Stop: Certificate of Correction Branch
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

This request for Certificate of Correction is made pursuant to 35 U.S.C. §254 and 37 C.F.R. §1.322(a) (PTO mistake) and 35 U.S.C. §255 and 37 C.F.R. §1.323 (Applicant's mistake) to correct mistakes inadvertently made in the subject patent. Please correct the subject patent according to the attached Certificate of Correction. Attached in duplicate is Form-1050, with at least one copy being suitable for printing.

CERTIFICATE OF MAILING (37 C.F.R. §1.8a)

I hereby certify that I have reasonable basis to expect and believe that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

June 3, 2004
Date of Deposit

Cynthia B. Pacheco
Cynthia B. Pacheco

IR1:1055440.1

A Certificate of Correction is requested in the above-referenced Patent under 35 U.S.C. §254 and 37 C.F.R. §1.322(a)) to correct mistakes made by the PTO in the printing of the claims. Applicant requests that the subject patent be corrected as follows:

Column 10:
Claim 36
Change "claim" to -- claim 30 -- .
Claim 37
Change "claim" to -- claim 36 --.

Support for these corrections can be found on page 8, claims 67-68 in the Amendment and Response filed on December 1, 2003 (Exhibit A) and in the Response dated February 9, 2004 (Exhibit B).

A Certificate of Correction is also requested under 35 U.S.C. §255 and 37 C.F.R. §1.323 (Applicant's mistake). Applicant requests that the subject patent be corrected as follows in order to correct grammatical mistakes.

Column 8
Claim 29
Delete "upon"

Column 10:
Claim 37
Delete "upon"

Please send the Certificate of Correction to John Kappos, O'Melveny & Myers LLP, 114 Pacifica, Suite 100, Irvine, California, 92618-3315, attorney of record for Assignees, Artemis Medical, Inc. The Commissioner is hereby authorized to charge Deposit Account No. **50-2862** in the amount of $100.00 and any additional fees that may be required with this submission.

Respectfully submitted,

Dated: June 3, 2004

By: Diane K. Wong
Diane K. Wong
Reg. No. 54,550
Attorneys for Applicant

O'MELVENY & MYERS LLP
114 Pacifica, Suite 100
Irvine, CA 92618
Phone: (949) 737-2900
Fax: (949) 737-2300

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

FULTON et al.

Serial No.: 10/027,157

Filed: December 20, 2001

For: BIOPSY LOCALIZATION METHOD AND DEVICE

Group Art Unit: 3736

Examiner: B. Szmal

AMENDMENT AND RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Office Action mailed June 30, 2003. Please amend the subject application as follows.

Amendments to the claims begin on page 2 of this paper.

Remarks begin on page 9 of this paper.

CERTIFICATE OF MAILING (37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, PO Box 1450 Alexandria, VA 22313-1450.

December 1, 2003
Date of Deposit

Cynthia B. Pacheco
Cynthia B. Pacheco

IR1:1049835.1

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of the Claims

1-3. (Canceled)

4. (Previously Amended) A soft target tissue localization device comprising:

a bioabsorbable element locatable at a soft target tissue site of a patient;

said bioabsorbable element being of a material which is palpably harder than the surrounding soft tissue at the soft target tissue site;

said bioabsorbable element having a pre delivery state and a post delivery state: and the bioabsorbable element having, a longest dimension of at least about 0.5 cm when in the post delivery state.

5. (Previously Amended) The device according to claim 4 wherein the bioabsorbable element comprises a bioabsorbable filament.

6. (Previously Amended) The device according to claim 4 further comprising a marker element in contact with the bioabsorbable element.

7. (Original) The device according to claim 6 wherein the marker element is a radiopaque marker element.

8. (Original) The device according to claim 6 wherein the marker element is located generally centrally within the bioabsorbable element.

9. (Original) The device according to claim 6 wherein the marker element is a radiopaque marker element located generally centrally within the bioabsorbable element.

10. (Original) The device according to claim the 6 wherein the marker element is a permanent marker element.

11. (Original) The device according to claim the 6 wherein the marker element is a temporary marker element.

12. (Previously Amended) The device according to claim 4 wherein the bioabsorbable element has margins, said margins being roughened so to help prevent migration of the bioabsorbable element within soft tissue of a patient.

13. (Original) The device according to claim 12 wherein the bioabsorbable element has filaments extending from the margins.

14. (Original) The device according to claim 13 wherein the filaments are of same material as the bioabsorbable element.

15. (Previously Amended) The device according to claim 1 wherein the bioabsorbable element is remotely visualizable in its post delivery state by at least one of ultrasound and mammography.

16. (Previously Amended) The device according to claim 4 wherein the bioabsorbable element is softer in a post delivery state than in a pre delivery state.

17. (Original) The device according to claim 1 wherein the bioabsorbable element is of a different hardness in a post delivery state as in a pre-delivery state.

18-36. (Canceled)

37. (Original) A biopsy localization method comprising:

taking a tissue sample from a biopsy site within a patient;

positioning a bioabsorbable element at the biopsy site;

testing the tissue sample; and

if the testing indicates a need to do so relocating the biopsy site by finding the bioabsorbable element by following a bioabsorbable thread, the thread extending from the patient's skin to the bioabsorbable element.

38. (Original) The method according to claim 37 wherein the positioning step is carried out using said bioabsorbable element and a radiopaque marker.

39. (Original) The device according to claim the 38 wherein the radiopaque marker element is a permanent marker element.

40. (Original) The device according to claim the 38 wherein the radiopaque marker element is a temporary marker element.

41. (Original) The method according to claim 37 wherein the remotely visualizing step is carried out to by at least one of ultrasound, mammography and MRI.

42. (Previously Amended) The method according to claim 37 further comprising the step of selecting the bioabsorbable element so that after positioning at the target site, the bioabsorbable element has a hardness of at least about 1.5 times as hard as the surrounding tissue.

43. (Original) The method according to claim 37 further comprising the step of effectively preventing blood from contacting the bioabsorbable element until the bioabsorbable element is positioned at the target site, the effectively preventing step being carried out by using a hemostatic bioabsorbable element having a non hemostatic biodegradable outer layer.

44. (Original) The method according the claim 37 further comprising the step of placing a marker element within the bioabsorbable element.

45. (Original) The method according the claim 37 further comprising the step of placing a marker element at a generally central location within the bioabsorbable element.

46-54. (Canceled)

55. (New) A target tissue localization device comprising:

an elongate tubular member having a proximal end, a distal end, and a lumen therebetween;

a bioresorbable body contained within the elongate tubular member, the bioresorbable body comprising polylactic acid and polyglycolic acid; and

a radiopaque marker carried by the bioresorbable body.

56. (New) The target tissue localization device of claim 55, wherein the bioresorbable body is remotely visualizable by at least one of ultrasound and mammography.

57. (New) The target tissue localization device of claim 55, wherein the radiopaque marker is contained within the bioresorbable body.

58. (New) The target tissue localization device of claim 55, wherein the bioresorbable body comprises at least one bioresorbable body.

59. (New) The target tissue localization device of claim 55, wherein the bioresorbable body swells upon contact with body fluid.

60. (New) The target tissue localization device of claim 59, wherein the bioresorbable body swells upon to substantially fill the biopsy site.

61. (New) A method for marking a biopsy cavity comprising the steps of:

providing a bioresorbable body having a radiopaque marker carried by the bioresorbable body, said bioresorbable body comprising polylactic acid and polyglycolic acid;

removing a biopsy specimen from the breast of a patient, thereby creating a biopsy site;

inserting the bioresorbable body into the biopsy site to mark the location of the biopsy site; and

testing the biopsy specimen.

62. (New) The method of claim 61, further comprising the step of relocating the biopsy site by detecting the radiopaque marker.

63. (New) The method of claim 61, wherein the bioresorbable body comprises at least one bioresorbable body.

64. (New) The method of claim 61, wherein the radiopaque marker is contained within the bioresorbable body.

65. (New) The method of claim 62, wherein the radiopaque marker is detected by mammography.

66. (New) The method of claim 62, wherein the radiopaque marker is detected by ultrasound.

67. (New) The method of claim 61, wherein the bioresorbable body swells upon contact with body fluid.

68. (New) The method of claim 67, wherein the bioresorbable body swells upon to substantially fill the biopsy site.

REMARKS

Reconsideration of the rejections set forth in the Office Action mailed June 30, 2003, is respectfully requested. Claims 1-3, 18-36, and 46-54 have been canceled. Claims 55-68 have been newly added. Claims 4-17, 37-45, and 55-68 remain pending in this case. Support for these amendments can be found in the specification at, e.g., page 3, lines 1-3; page 6, lines 10-12; page 8, lines 4-9; and page 8, lines 20-25. Therefore, these amendments are made without introducing new matter.

Art Rejections

Claims 19, 23, 46, and 50 were rejected under 35 U.S.C. § 102(b) as being alleged anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being allegedly obvious over Haaga (U.S. Patent 5,487,392). Applicants have cancelled claims 19, 23, 46, and 50. Therefore, these rejections are now moot. Applicants also point out that Haaga does not teach or suggest a "*bioresorbable body comprising polylactic acid and polyglyolic acid*" or the inclusion of "*a radiopaque marker carried by the bioresorbable body*," as required by the newly added claims.

Allowable Subject Matter

Applicants gratefully acknowledge the examiner's indication that claims 2-17 and 37-45 are allowable.

For all the foregoing reasons, Applicants assert the claims are in condition for allowance. Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicants' undersigned representative at (949) 737-2900. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,
O'MELVENY & MYERS LLP

Dated: November 26, 2003

By: Diane K Wong
Diane K. Wong
Reg. No. 54,550
Attorneys for Applicants

JCK/DKW/cp

O'Melveny & Myers LLP
114 Pacifica, Suite 100
Irvine, CA 92618-3315
(949) 737-2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

FULTON et al.

Serial No.: 10/027,157

Filed: December 20, 2001

For: BIOPSY LOCALIZATION METHOD AND DEVICE

Group Art Unit: 3736

Examiner: B. Szmal

RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Office Action mailed February 2, 2004. Please amend the subject application as follows.

Listing of the claims begin on page 2 of this paper.

Remarks begin on page 9 of this paper.

CERTIFICATE OF MAILING (37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted to (703) 872-9306 on the date shown below addressed to the Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

February 9, 2004
Date of Deposit

Cynthia B. Pacheco
Cynthia B. Pacheco

IR1:1052214.1

LISTING OF THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-3. (Canceled)

4. (Previously Presented) A soft target tissue localization device comprising:

a bioabsorbable element locatable at a soft target tissue site of a patient;

said bioabsorbable element being of a material which is palpably harder than the surrounding soft tissue at the soft target tissue site;

said bioabsorbable element having a pre delivery state and a post delivery state: and the bioabsorbable element having, a longest dimension of at least about 0.5 cm when in the post delivery state.

5. (Previously Presented) The device according to claim 4 wherein the bioabsorbable element comprises a bioabsorbable filament.

6. (Previously Presented) The device according to claim 4 further comprising a marker element in contact with the bioabsorbable element.

7. (Original) The device according to claim 6 wherein the marker element is a radiopaque marker element.

8. (Original) The device according to claim 6 wherein the marker element is located generally centrally within the bioabsorbable element.

9. (Original) The device according to claim 6 wherein the marker element is a radiopaque marker element located generally centrally within the bioabsorbable element.

10. (Original) The device according to claim the 6 wherein the marker element is a permanent marker element.

11. (Original) The device according to claim the 6 wherein the marker element is a temporary marker element.

12. (Previously Presented) The device according to claim 4 wherein the bioabsorbable element has margins, said margins being roughened so to help prevent migration of the bioabsorbable element within soft tissue of a patient.

13. (Original) The device according to claim 12 wherein the bioabsorbable element has filaments extending from the margins.

14. (Original) The device according to claim 13 wherein the filaments are of same material as the bioabsorbable element.

15. (Previously Presented) The device according to claim 1 wherein the bioabsorbable element is remotely visualizable in its post delivery state by at least one of ultrasound and mammography.

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17. (Original) The device according to claim 1 wherein the bioabsorbable element is of a different hardness in a post delivery state as in a pre-delivery state.

18-36. (Canceled)

37. (Original) A biopsy localization method comprising:

taking a tissue sample from a biopsy site within a patient;

positioning a bioabsorbable element at the biopsy site;

testing the tissue sample; and

if the testing indicates a need to do so relocating the biopsy site by finding the bioabsorbable element by following a bioabsorbable thread, the thread extending from the patient's skin to the bioabsorbable element.

38. (Original) The method according to claim 37 wherein the positioning step is carried out using said bioabsorbable element and a radiopaque marker.

39. (Original) The device according to claim the 38 wherein the radiopaque marker element is a permanent marker element.

40. (Original) The device according to claim the 38 wherein the radiopaque marker element is a temporary marker element.

41. (Original) The method according to claim 37 wherein the remotely visualizing step is carried out to by at least one of ultrasound, mammography and MRI.

42. (Previously Presented) The method according to claim 37 further comprising the step of selecting the bioabsorbable element so that after positioning at the target site, the bioabsorbable element has a hardness of at least about 1.5 times as hard as the surrounding tissue.

43. (Original) The method according to claim 37 further comprising the step of effectively preventing blood from contacting the bioabsorbable element until the bioabsorbable element is positioned at the target site, the effectively preventing step being carried out by using a hemostatic bioabsorbable element having a non hemostatic biodegradable outer layer.

44. (Original) The method according the claim 37 further comprising the step of placing a marker element within the bioabsorbable element.

45. (Original) The method according the claim 37 further comprising the step of placing a marker element at a generally central location within the bioabsorbable element.

46-54. (Canceled)

55. (Previously Presented) A target tissue localization device comprising:

an elongate tubular member having a proximal end, a distal end, and a lumen therebetween;

a bioresorbable body contained within the elongate tubular member, the bioresorbable body comprising polylactic acid and polyglycolic acid; and

a radiopaque marker carried by the bioresorbable body.

56. (Previously Presented) The target tissue localization device of claim 55, wherein the bioresorbable body is remotely visualizable by at least one of ultrasound and mammography.

57. (Previously Presented) The target tissue localization device of claim 55, wherein the radiopaque marker is contained within the bioresorbable body.

58. (Previously Presented) The target tissue localization device of claim 55, wherein the bioresorbable body comprises at least one bioresorbable body.

59. (Previously Presented) The target tissue localization device of claim 55, wherein the bioresorbable body swells upon contact with body fluid.

60. (Previously Presented) The target tissue localization device of claim 59, wherein the bioresorbable body swells upon to substantially fill the biopsy site.

61. (Previously Presented) A method for marking a biopsy cavity comprising the steps of:

providing a bioresorbable body having a radiopaque marker carried by the bioresorbable body, said bioresorbable body comprising polylactic acid and polyglycolic acid;

removing a biopsy specimen from the breast of a patient, thereby creating a biopsy site;

inserting the bioresorbable body into the biopsy site to mark the location of the biopsy site; and

testing the biopsy specimen.

62. (Previously Presented) The method of claim 61, further comprising the step of relocating the biopsy site by detecting the radiopaque marker.

63. (Previously Presented) The method of claim 61, wherein the bioresorbable body comprises at least one bioresorbable body.

64. (Previously Presented) The method of claim 61, wherein the radiopaque marker is contained within the bioresorbable body.

65. (Previously Presented) The method of claim 62, wherein the radiopaque marker is detected by mammography.

66. (Previously Presented) The method of claim 62, wherein the radiopaque marker is detected by ultrasound.

67. (Previously Presented) The method of claim 61, wherein the bioresorbable body swells upon contact with body fluid.

68. (Previously Presented) The method of claim 67, wherein the bioresorbable body swells upon to substantially fill the biopsy site.

REMARKS

Reconsideration of the rejections set forth in the Office Action mailed February 2, 2004, is respectfully requested. Claims 4-17, 37-45, and 55-68 remain pending in this case.

Art Rejections

Claims 55-60 were rejected under 35 U.S.C. § 102(e) as being alleged anticipated by Corbitt, Jr. et al. (USP 6,214,045). Claims 61-68 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Foerster et al. (USP 6,228,055) in view of Corbitt, Jr. et al.

As discussed with Examiner Szmal with respect to related U.S. Application Serial No. 09/900,801 (Our Ref: 032,290-006), applicants respectfully assert that Corbitt is not prior art to the claims pending herein. Specification support for all claims 55-68 can be found in U.S. Application Serial No. 60/090,243, filed June 22, 1998, the benefit of which is claimed in the present application. (See, e.g., page 7, lines 16-21, page 9, lines 11-15, and Figs. 3 and 4). Corbitt is not prior art because Corbitt did not describe, before June 22, 1998, a biopsy site marker comprising polylactic acid and polyglycolic acid or a method of using the same. Therefore, all claim rejections should be withdrawn.

Allowable Subject Matter

Applicants gratefully acknowledge the examiner's indication that claims 4-17 and 37-45 are allowable.

For all the foregoing reasons, Applicants assert the claims are in condition for allowance. Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicants' undersigned representative at (949) 737-2900. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,
O'MELVENY & MYERS LLP

Dated: 2/7/04 By: John Kappos
John Kappos
Reg. No. 37,861
Attorneys for Applicants

JCK/DKW/cp

O'Melveny & Myers LLP
114 Pacifica, Suite 100
Irvine, CA 92618-3315
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-O'MELVENY&MYERS LLP IRV04-

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O'MELVENY & MYERS LLP

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RETURN FAX NUMBER:
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TELEPHONE NUMBER:
(949) 737-2900

MESSAGE

Re: **Fulton et al.**
U.S. Application Serial No. 10/027,157

Attorney Docket No. 032,290-007
(formerly docket ARTM 1000-6

Document(s) attached:

1. Response – 10 pages

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(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,730,042 B2

DATED : May 4, 2004

INVENTOR(S) : Fulton et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 8, line 60

Claim 29
Delete "upon".

Column 10, line 5

Claim 36
Change "claim" to -- claim 30 --.

Col. 10, line 7

Claim 37
Change "claim" to -- claim 36 --.
Delete "upon".

MAILING ADDRESS OF SENDER:

John Kappos, Esq.
O'MELVENY & MYERS LLP
114 Pacifica, Suite 100
Irvine, CA 92618

PATENT NO. 6,730,042 B2

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14 JUN 2004

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(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,730,042 B2

DATED : May 4, 2004

INVENTOR(S) : Fulton et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 8

Claim 29
Delete "upon".

Column 10

Claim 36
Change "claim" to -- claim 30 --.

Claim 37
Change "claim" to -- claim 36 --.
Delete "upon".

MAILING ADDRESS OF SENDER:

John Kappos, Esq.
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114 Pacifica, Suite 100
Irvine. CA 92618

PATENT NO. 6,730,042 B2

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14 JUN 2004